TAB B

TUCKER ELLIS & WEST LLP
ATTORNEYS AT LAW

1150 Huntington Bldg. 925 Euclid Avenue Cleveland, Ohio 44115-1414
phone 216.592.5000 fax 216.592.5009 Web: www.tuckerellis.com

CLEVELAND COLUMBUS LOS ANGELES SAN FRANCISCO

Direct Dial: 216.696.4835
Email: michael.anderton@tuckerellis.com

September 29, 2009

VIA E-MAIL

Harry Bell
Bell & Bands, PLLC
30 Capitol Street
P.O. Box 1723
Charleston, West Virginia 25326
(hfbell@belllaw.com)

Fred Thompson
Motley Rice
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(fthompson@motleyrice.com)

Carl Frankovitch
Frankovitch, Anetakis, Colantonio & Simon
337 Penco Rd.
Weirton, WV 26062
(carln@facslaw.com)

Re: Digitek® Product Liability Litigation (MDL No. 1968)
September 21, 2009 Correspondence Concerning Discovery Issues

Gentlemen:

This letter will respond to your September 21, 2009 correspondence regarding issues you have raised with the non-class action discovery responses of the Actavis Defendants. The issues you raised regarding class action discovery responses were addressed in Kristen Mayer's September 25, 2009 letter to you.

Non-Compliance With Rule 37

As noted below, we would welcome a prompt discussion on adjusting PTO #16 dates if you would like to recommence the meet and confer process terminated by the filing of your September 24, 2009 motions.

As an initial matter, we note the timing of the circumstances surrounding the PSC raising discovery issues with the Defendants, because we believe the PSC has not complied with its obligations under Rule 37. As you know, the PSC asked for a meet and confer concerning alleged deficiencies in Defendants' discovery responses the week of September 14, 2009. The Defendants promptly responded and set up what we believed would be a telephone meet and

confer on September 18, 2009. During that call the PSC merely alleged very generally that there were deficiencies in Defendants' discovery responses and was unable to identify any specific deficiencies that Defendants could evaluate and respond to in detail. Defendants suggested that the PSC prepare a written correspondence setting forth specific perceived deficiencies and present it to the Defendants, and promised to review any such letter and promptly respond. In short, the September 18, 2009 telephone conference was not and could not have been a meet and confer because the PSC never identified any specific discovery response deficiency which Defendants could address.

The PSC provided Defendants with a specific list of alleged deficiencies by letter which was received at 5:55 pm on September 21, 2009. That letter, to which this letter is responsive, was the first time Defendants had any specificity regarding discovery responses the PSC claims are deficient. Nevertheless, 3 days later, on September 24, 2009, the PSC filed a Motion to Compel responses and production that are contemplated with your September 21, 2009 letter. The Motion was filed without any communication between the PSC and Defendants on the specific issues raised for the first time in your September 21, 2009 letter and without even seeking a discussion on those issues. The PSC has thus far declined to withdraw the Motion to Compel despite Defendants' request to do so.

Under those circumstances, it cannot reasonably be said that the PSC engaged in or even sought a meet and confer with Defendants on specific alleged discovery deficiencies. The PSC plainly has not satisfied its Rule 37 obligations.

MDL Discovery Background

The scope and timing of discovery in this litigation is set forth in and governed by PTO Nos. 12, 16, 27, and 37. Under PTO 16, Defendants were required to voluntarily produce certain documents by September 1, 2009. PTO 16 is silent with respect to the deadline for further production of documents, such as documents being produced in response to specific discovery requests from Plaintiffs. Since the documents specifically enumerated in PTO 16 were and are being produced on a rolling basis, it is only logical that documents produced in response to specific discovery requests also would be produced on a rolling basis. Indeed, Matt Moriarty has repeatedly told members of the PSC that Actavis would be producing documents that are not contemplated by PTO 16 on a rolling basis after September 1, 2009.

This is particularly true when considering the facts and circumstances of the timing of discovery requests received from Plaintiffs, and also Plaintiffs' participation in the processes necessary to allow Actavis to begin producing documents. As you are aware, Defendants asked the PSC in late 2008 to participate in developing search and culling terms that would be used to identify and extract potentially relevant documents. Despite repeated efforts to engage the PSC

in that discussion, over a nearly six month period, the PSC declined to participate substantively until March 2009.

Actavis had segregated and held more than 1,000,000 documents as being potentially relevant to this litigation under its litigation hold obligations. Actavis could not begin the process of identifying documents that are actually responsive to discovery requests until the search and culling terms were finalized. By the time that occurred, Actavis was in the process of locating and preparing for production the documents specifically identified in PTO 16. As you know, Actavis began producing the non-electronic documents described by PTO 16 in April and continued those productions into July, 2009. The electronic documents contemplated by PTO 16 also could not be identified until Actavis applied the search and culling terms agreed to by the parties in April 2009.

Since its last production, on July 16, 2009, Actavis has been actively engaged in reviewing and processing electronic documents. This requires that Actavis review hundreds of thousands of documents for relevance, responsiveness, and privilege. Some delay was added to the process by your letter identifying 17 specific individuals whose documents you sought first to allow you to prepare for depositions of those individuals as Actavis was required to shift some of its focus and priority to the documents of those individuals from the document review and processing that was ongoing at that time. Actavis continues to actively review and process an initial production of documents that had begun before receiving your letter identifying the 17 priority custodians and Actavis hopes to make its initial production of those documents in the next 14 days. After this initial production, Actavis intends to produce all documents of the 17 specific custodians to enable the PSC to commence depositions of those individuals. Actavis will then complete production of the documents of all remaining custodians.

Actavis concedes it has not been able to produce all documents contemplated by PTO 16. This is due to the fact that Actavis has not yet been able to process and produce all electronic documents that might be contemplated by PTO 16, including things such as emails and other electronic correspondence. That is in part because of the delay of the PSC in participating in the process of developing search terms and also in part because of the substantive volume of documents that must be processed and then reviewed. We assure you Actavis is working diligently to continue and complete production of all relevant documents in this litigation as quickly as possible.

On September 24, 2009, you also filed a Motion to Extend Deadlines in PTO #16. In light of the fact that we are still working to produce documents we understand and agree that there are dates in PTO #16 that must be moved back and as Dick Dean indicated in our September 18 phone call, the Actavis defendants are willing to continue to discuss specifics in that regard in a call with you. We have already indicated our position on the Class Action briefing schedule that

only a two week extension is in order because the document production does not implicate that issue. We understand that many of the other dates in PTO #16 will need to be adjusted by moving them back by several months.

MDL Discovery Scope

The scope of documents and information Actavis is required to produce is governed by PTO Nos. 12, 16, 27, and 37. Under PTO 12 (the Stipulated Protective Order), the PSC expressly agreed that Defendants may redact "*Any* information relating to products other than Digitek®, unless *manufacturing information* about a product other than Digitek® is reasonably related to Digitek® manufacturing[.]" (ECF No. 71 at Section II.F.4) The meaning of this provision in PTO 12 has been clarified by the court in PTO Nos. 27 and 37, where the court allowed a "*limited* expansion of the *scope of discovery*." (ECF No. 150 at 15; ECF No. 185.) Under that Order, Plaintiffs are entitled to discovery in this litigation concerning information about Digitek® and also to "records of Little Falls production and the use of equipment for products other than Digitek®, which immediately preceded the use of that equipment for the production of Digitek®." (ECF No. 150 at 15.) Thus, information about Digitek® and the "batch record" for those limited batches of non-Digitek® product described in PTO 27 comprise the entire scope of information about which Plaintiffs are entitled to discovery in this litigation. (ECF No. 150; ECF No. 185.)

With this background in mind, Actavis hereby responds to each point in your correspondence of September 21, 2009, to the extent we are capable of discerning your intention under each point in your letter. The numbers below correspond to the numbering in your letter.

1. **Substantive Responsive Responses by Actavis Inc. and Actavis Elizabeth LLC**

Actavis, Inc. and Actavis Elizabeth LLC were not involved in the manufacture or the distribution of Digitek®. Neither company has any substantive information relating to Digitek®. As a result, neither company has responded to any substantive discovery requests.

2. **Privilege and Redaction Log**

You have indicated that Actavis has produced neither a privilege log nor relevant redaction logs relating to its prior productions. As we have told you repeatedly, no privilege log has been produced because Actavis has not withheld any documents due to privilege. The redaction logs for document productions served on June 5, June 12, June 24, and July 16, 2009 were produced on September 23, 2009. We apologize for the oversight in not providing these redaction logs previously.

3. **PTO #16 Documents**

Your letter correctly notes that not all documents contemplated by PTO 16 have been produced. Actavis is still processing electronic documents that might fall under the scope of PTO 16 and will produce the electronic documents that are responsive to PTO 16 as soon as possible.

We note, however, that some of the examples you cite in your letter are actually not documents that are contemplated by PTO 16. For example, you reference scribe notes relating to FDA inspections and internal records of telephone conversations with the FDA. Internal company notes and records of telephone conversations are not provided to the FDA. Such documents, therefore, are not "between Actavis and the FDA" and are not contemplated by PTO 16; rather, any such documents would be produced in response to relevant discovery requests, if any. Moreover, to the extent any such documents are produced, they will be redacted to remove references to other drugs, as is expressly permitted by PTO 12.

4. **Production of Documents in Response to Discovery Requests**

As noted above, we disagree with your reading of PTO 16. We believe all parties understood when negotiating PTO 16 that all document productions in this litigation would be on a rolling basis. Actavis is not "withholding" documents, as the ordinary meaning of that term implies. Actavis is processing documents as quickly as possible and will produce documents that are responsive to discovery requests as soon as possible.

Requests for Production Nos. 7, 8, 46, 48, 49, 50, 51, 52, 53, 55, 68, and 69

As we have indicated in our discovery responses to these requests for production, all responsive documents will be produced. Some responsive documents have already been produced. Any remaining documents will be produced as soon as possible.

Requests for Production Nos. 10, 14, and 15

As you note in your letter, the batch records for all of the recalled batches have been produced. Any aspect of non-conformance relating to the tablets in any of those batches will be reflected in those records. As for non-batch record documents relating to non-conformance of Digitek®, such as internal communications or memos, these documents are a part of the electronic documents that are currently being reviewed and processed. These documents will be produced as soon as possible. Consistent with PTO Nos. 12, 27, and 37, however, these documents will be limited to documents related to Digitek®.

Request for Production No. 13

As we indicated above concerning the documents contemplated generally by PTO 16, the electronic documents that are responsive to Request for Production No. 13 will be produced as soon as we can process them and prepare them for production. We note, however, that we will be producing only documents that relate to Digitek® or that we are required to produce under PTO Nos. 27 and 37. Documents such as notes or correspondence that contain references to non-Digitek® drugs will be redacted according to PTO 12.

Requests for Production Nos. 16, 17, and 43

These requests seek communication, internal and external, regarding the recall of Digitek®. As we have indicated in our initial responses, all non-privileged responsive documents will be produced. We are trying to identify responsive documents, process them, and produce them as quickly as possible.

Request for Production No. 73

Actavis has not provided a substantive response to Request No. 73 because Actavis has objected to this request. IT helpdesk logs have no relevance to a product defect case and are not reasonably calculated to lead to the discovery of admissible evidence.

Requests for Production Nos. 74, 75, 76, 77, and 81

These requests seek documents related to various investigations. As your letter explicitly acknowledges, Actavis intends to produce all non-privileged relevant documents as soon as possible, as we indicated in our initial response to these requests.

5. **Responses to Interrogatories**

Interrogatory No. 3

In response to Interrogatory No. 3, Actavis has referred Plaintiffs to training records which will reflect the information that is responsive to Interrogatory No. 3. Your letter claims this response is unacceptable; however, Federal Rule 33(d) explicitly permits a responding party to answer an interrogatory by referring to records containing information that is responsive to the interrogatory. The burden of deriving or ascertaining the answer to Interrogatory No. 3 by reviewing the training records provided is substantially the same for Plaintiffs as it would be for Actavis. Actavis' response to Interrogatory No. 3 is expressly permitted by Rule 33(d) and is not deficient.

Interrogatory No. 23

Actavis' response to Interrogatory No. 23 is complete. The Bates ranges cited by Actavis in its response to Interrogatory No. 23 refer to the Digitek® Annual Product Reviews for 5 years. Each annual product review contains information about rejected batches, including the information about the circumstances surrounding the decision to reject the batch. Although your letter indicates Actavis has inappropriately referred you to more than 1,000 pages of documents, in reality this comprises a mere 5 documents. If you review those documents, you will quickly be able to glean the information that is responsive to Interrogatory No. 23. Actavis' response to this Interrogatory again is sufficient under Rule 33(d).

Interrogatory No. 28

Actavis has not redacted the list of Digitek® raw materials. Actavis has, however, redacted the identity of the manufacturer of each raw material. Such information is confidential and proprietary business information and has been redacted under PTO 12, Section II.F.2. The identity of the manufacturer of raw materials is not relevant to this litigation. This is not a cross contamination case or a case involving any claim of defective raw materials, other than perhaps the active pharmaceutical ingredient for Digitek®, digoxin. The scope of non-Digitek® information that is subject to discovery is limited to what is set forth in PTO Nos. 27 and 37.

Interrogatory No. 34

Your claim that the response to Interrogatory No. 34 is deficient is another example of choosing to not review documents that have been produced and identified. The information that is responsive to this Interrogatory is plainly set forth in the Equipment Use and Cleaning Logs, which have been produced unredacted. Referring you to these documents is specifically permitted by Rule 33(d). It is incumbent on Plaintiffs to actually review the produced documents and the burden for you to review the documents and learn the information is no more onerous than it would be if Actavis reviewed the documents and provided the information you seek in Interrogatory No. 34.

Interrogatory No. 35

Your claim of deficiency regarding Interrogatory No. 35 is that Defendants have not identified the Bates ranges for the lab notebooks of the analysts identified by Actavis in response to Interrogatory No. 35. Actavis is not required to do so. The lab notebook pages containing testing information for each recalled batch of Digitek® have been produced. It is just as easy for the Plaintiffs to determine the lab notebook page Bates ranges as it is for Actavis to do so.

Actavis is not obligated to review those documents and find those Bates ranges.

Interrogatory No. 41

Your claim of deficiency regarding Interrogatory No. 41 is illogical. Interrogatory No. 41 asks for the distributor for each recalled batch of Digitek®. Actavis' response is complete and accurate – each recalled batch of Digitek® was distributed by Mylan Pharmaceuticals, Inc., Mylan Bertek Pharmaceuticals, or UDL Laboratories, Inc.

If you have any questions about any aspect of this correspondence, please do not hesitate to contact me or Matt Moriarty. We welcome the opportunity to further discuss any aspect of this letter, your September 21, 2009 letter, or the issues raised by your Motion to Compel. As noted at the outset of this correspondence, we would welcome a discussion on adjusting dates in PTO #16 if you would like to recommence the meet and confer process you terminated with the filing of your motions.

Very truly yours,

/s/ Michael Anderton

Michael Anderton

cc (via e-mail): Dick Dean
Matt Moriarty
Madeleine McDonough
Harvey L. Kaplan
Ericka Downie
Meghan Johnson Carter